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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/659,928

09/11/2003

Haijime Makiuchi

JG-TT-5140C/500568.20032

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03/22/2004

REED SMITH, LLP

ATTN: PATENT RECORDS DEPARTMENT

599 LEXINGTON AVENUE, 29TH FLOOR

NEW YORK, NY 10022-7650

EXAMINER

WALLENHORST, MAUREEN

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

10/659,928

Applicant(s)

MAKIUCHI ET AL.

Examiner

Maureen M. Wallenhorst

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2 and 3 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 2 and 3 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

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1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on May 30, 2001. It is noted, however, that applicant has not filed a certified copy of the Japanese application as required by 35 U.S.C. 119(b).
2. The disclosure is objected to because of the following informalities: On page 1 of the specification in the first sentence after the title, the phrase --, now abandoned—should be inserted after the phrase “Application serial no. 10/159,081, filed May 29, 2002” so as to update the status of the parent application.

Appropriate correction is required.

3. Claims 2-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is indefinite since it is not clear whether the blood component is measured in the serum recited on line 2 by applying the serum to the dry analytical element, or whether the blood component is measured in a blood sample separate from the serum that is applied to the dry analytical element. For examination purposes, claim 2 will be interpreted as a method of measuring one of the recited analytes in the control serum by applying the control serum to the dry analytical element. The serum recited in claim 2 is also indefinite since it is not clear whether no dialysis is performed on the serum before or after the step of freezing or freeze drying.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 2-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Yanagihara et al.

Yanagihara et al teach of a dry analytical element in the form of a dry gel chromatographic packing. Yanagihara et al teach of a method in which a sample solution of a freeze-dried human control serum is applied to the dry gel chromatographic packing material in a column. The analytes of albumin, creatinine and uric acid are analyzed in the control serum upon eluting through the column. See lines 66-68 in column 12 and lines 1-3 in column 13 of Yanagihara et al. Yanagihara et al make no mention that the freeze-dried control serum undergoes any dialysis process.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 2-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terashima et al in view of Hundt et al.

Terashima et al teach of a dry analytical element for measuring the activity of alkaline phosphatase in a sample. In example 6 taught by Terashima et al, control human serums having known amounts of alkaline phosphatase therein are spotted onto the dry analytical element and analyzed. See lines 50-60 in column 11 of Terashima et al. Terashima et al fail to teach that the control serums are frozen or freeze-dried with no dialysis before use in testing the dry analytical element.

Hundt et al teach of a control serum having a definite amount of alkaline phosphatase therein. The control serum is lyophilized which is the same as freeze-drying since both serve to eliminate water from the serum. Hundt et al make no mention that the freeze-dried control serum undergoes any dialysis process.

Based upon a combination of Terashima et al and Hundt et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to freeze-dry or lyophilize the control serum containing alkaline phosphatase taught by Terashima et al before its use in testing of a dry analytical element since Hundt et al teaches that control serums containing

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alkaline phosphatase are preferentially lyophilized for storage so as to maintain a prolonged viability.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Kitajima and Mori et al who teach of the measurement of analytes in control serums on dry analytical elements; and Stone, Terano et al, Sugiyama et al and Pinto et al which were cited in the parent application.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

March 15, 2004

Maureen M. Wallenhorst
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PRIMARY EXAMINER
GROUP 1000 1700